A Prospective Randomized Study on Suprapatellar and Infrapatellar Intramedullary Nailing for Proximal Tibia Extra-Articular Fractures.

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ABSTRACT

Introduction: Intramedullary nailing is the gold standard for proximal tibia extra-articular fractures. The optimal approach, suprapatellar or infrapatellar, remains debated. This study compares the functional and radiological outcomes of these two techniques.

Aim and Objective: To evaluate and compare the functional and radiological outcomes of suprapatellar and infrapatellar intramedullary nailing in proximal tibia extra-articular fractures.

Materials and Methods: A randomized controlled trial was conducted with 40 patients, divided into infrapatellar (n=20) and suprapatellar (n=20) groups. Functional outcomes were assessed at 1, 3, and 6 months using the Lower Extremity Functional Scale (LEFS) and Lysholm Knee Score. Pain was evaluated with the Visual Analog Scale (VAS), and radiographic alignment and fracture healing were analyzed. Statistical analysis included t-tests.

Results: The suprapatellar group demonstrated significantly better functional outcomes at 3 and 6 months. At 6 months, the suprapatellar group had a significantly higher Lysholm Knee Score (92.2 ± 5.35) compared to the infrapatellar group (87.95 ± 5.34, p=0.016). Similarly, the LEFS score was higher in the suprapatellar group (88.20 ± 4.54) than the infrapatellar group (82.10 ± 5.86, p=0.025). Pain was significantly lower in the suprapatellar group, with a mean VAS score of 2.0 (±0.30) versus 2.50 (±0.50) in the infrapatellar group (p=0.001).

Conclusion: Suprapatellar intramedullary nailing yielded superior functional outcomes and reduced pain compared to the infrapatellar approach in proximal tibia extra-articular fractures.

Introduction

Proximal tibia extra-articular fractures represent a significant challenge in orthopedic trauma, impacting patients across a wide age spectrum and often leading to substantial morbidity. These fractures, occurring proximal to the tibial diaphysis and outside the articular surface, are frequently the result of high-energy trauma, such as motor vehicle accidents or falls from height, though low-energy mechanisms can also contribute, particularly in the elderly population with osteoporotic bone. Effective management of these fractures is crucial for restoring limb function, minimizing complications, and facilitating timely return to pre-injury activity levels. Intramedullary nailing (IMN) has emerged as the gold standard for surgical management of proximal tibia extra-articular fractures, offering several advantages over alternative fixation methods. IMN provides stable fixation, allows for early weight-bearing, and minimizes soft tissue disruption, thereby promoting fracture healing and functional recovery. The technique involves inserting a metal nail into the medullary canal of the tibia, providing internal support and stability to the fracture site. However, the optimal entry point

and nailing technique for proximal tibia fractures remain a subject of ongoing debate. Traditionally, the infrapatellar approach, involving an entry point just distal to the tibial tuberosity, has been widely used. This approach offers a relatively straightforward surgical technique and minimizes disruption of the extensor mechanism. However, it can be technically challenging in proximal fractures, particularly those with significant comminution or extension into the metaphysis. In recent years, the suprapatellar approach has gained increasing popularity as an alternative to the infrapatellar technique. This approach, involving an entry point through the patellar tendon with the knee in flexion, offers several potential advantages. It allows for better visualization of the proximal tibia, facilitates easier nail insertion, and reduces the risk of malalignment, particularly in proximal fractures. Furthermore, it minimizes disruption of the extensor mechanism, potentially leading to improved knee function and reduced anterior knee pain. Despite the growing acceptance of the suprapatellar approach, there is a paucity of high-quality evidence comparing its outcomes with those of the traditional infrapatellar technique. Existing studies have reported conflicting results, with some suggesting superior functional and radiological outcomes with the suprapatellar approach, while others have found no significant differences between the two techniques. This lack of consensus highlights the need for further research to clarify the relative merits of these two approaches. Functional outcomes following IMN for proximal tibia fractures are typically assessed using validated scoring systems, such as the Lower Extremity Functional Scale (LEFS) and the Lysholm Knee Score. These tools evaluate pain, function, range of motion, and gait, providing a comprehensive assessment of patient recovery. Radiological outcomes, including fracture healing, alignment, and the presence of complications such as malunion or nonunion, are also critical considerations in evaluating surgical efficacy. Post-operative complications, including infection, malalignment, knee pain, and implant-related issues, are important factors to consider when comparing surgical techniques. Anterior knee pain, in particular, has been a significant concern following IMN, potentially impacting patient satisfaction and functional recovery. The choice of nailing approach may influence the incidence and severity of anterior knee pain, highlighting the importance of evaluating this outcome in comparative studies. This prospective study aims to compare the functional and radiological outcomes of suprapatellar and infrapatellar intramedullary nailing for proximal tibia extra-articular fractures. By prospectively evaluating a cohort of patients undergoing IMN, we seek to determine if there are any statistically significant differences in functional outcomes (as measured by the LEFS and Lysholm Knee Score), radiological outcomes (fracture healing and alignment), and the incidence of complications between the two approaches. The findings of this study will contribute to the existing body of knowledge and provide valuable insights to guide clinical decision-making in the management of proximal tibia extra-articular fractures. By clarifying the relative merits of the suprapatellar and infrapatellar approaches, this research will aid in refining surgical techniques and rehabilitation protocols, ultimately improving patient outcomes and quality of life. Furthermore, this study will address the current uncertainty surrounding the optimal nailing technique, providing evidence-based recommendations for orthopedic surgeons. The results will allow for surgeons to make informed decisions about the best surgical approach for their patients, considering the individual fracture characteristics and patient factors.

Materials and Methods

Study Design and Setting:

This prospective, randomized controlled study was conducted over 24 months at the Department of Orthopaedics, Bhaskar Medical College, Moinabad, Telangana.

Patient Selection:

Forty patients with proximal tibia extra-articular fractures were enrolled.

Inclusion Criteria:

- Age 20-70 years.
- Closed fractures of the proximal tibia.
- Segmental tibia fractures.
- All extra-articular fractures of the proximal tibia.
- Informed consent.

Exclusion Criteria:

- Pediatric tibia fractures.
- Pathological tibia fractures.
- Uncontrolled diabetes or hypertension.
- Deranged hepatic or renal function.
- Intra-articular knee or ankle fractures.
- Stiff knee.
- Open/compound fractures.
- Pre-existing knee osteoarthritis or prior knee injury.
- Refusal to provide consent.

Randomization:

Patients were randomly assigned (1:1) using a random number generator to:

- Suprapatellar nailing group (n=20).
- Infrapatellar nailing group (n=20).

Operative Protocol:

- Anesthesia: Spinal or general anesthesia.
- Preparation: Standard surgical scrubbing and draping.
- Surgery: Performed by experienced orthopedic surgeons using a standard intramedullary nailing system.

Surgical Approaches:

- **Infrapatellar:**

  - Skin incision infrapatellar.
  - Entry point 2mm medial to the lateral proximal tibia spine (AP) and adjacent/anterior to the medial proximal tibia plateau (lateral).
- **Suprapatellar:**
  - 1.5-2 cm longitudinal skin incision 1 cm above the patellar base.
  - Longitudinal split in the quadriceps tendon.
- All patients received preoperative antibiotics and closed reduction under fluoroscopic guidance.
- Postoperative radiographs confirmed implant placement and fracture reduction.

Outcome Measures:

- **Functional Outcomes (1, 3, 6 months):**
  - Lysholm Knee Score (stability, pain, function).
  - Lower Extremity Functional Scale (LEFS) (daily activities).
- **Pain Assessment (1, 3, 6 months):**
  - Visual Analog Scale (VAS) (0-10).
- **Radiological Outcomes:**
  - Fracture union (callus formation across ≥3 cortices).
  - Fracture alignment (varus/valgus, anterior/posterior angulation).

Statistical Analysis:

- [Software, e.g., SPSS or R].
- Continuous variables (functional scores, VAS, operative time): Independent t-tests.
- Categorical data: Chi-square test.
- $P < 0.05$: Statistical significance.

Sample Size Calculation:

- 20 patients/group (80% power, $p<0.05$) based on previous studies.

Post-Operative Protocol:

- **Immediate Post-Operative Care (Day 1-Week 2):**
  - Oral analgesics (acetaminophen, NSAIDs).
  - Postoperative X-rays.
  - 24-hour antibiotics.
  - Thromboprophylaxis (LMWH or DOACs).
  - Wound care, suture/staple removal (12-14 days).
  - Passive range of motion (ROM) exercises (knee, ankle).
  - Gentle quadriceps strengthening.
- **Weight-Bearing Protocol:**
  - 1 month: Partial weight-bearing (20-30%) with crutches/walker. Active ROM exercises, 90-degree knee flexion by week 6.
  - 6-12 weeks: Full weight-bearing as tolerated (clinical/radiological signs). Radiographs at 1 month, progression to full weight-bearing by 12 weeks. Strengthening exercises, functional activities.

- 12-18 weeks: Full weight bearing without assistance with good radiographic signs.
- 18-24 weeks: Full weight bearing without assistive devices. Resumption of ADLs, light jogging, non-impact sports.

Results:

Functional Outcomes:

Lysholm Knee Score:

- The suprapatellar group consistently demonstrated higher Lysholm Knee Scores, indicating superior knee function compared to the infrapatellar group.
- **1 month:** Suprapatellar: 68.8 ± 5.51, Infrapatellar: 65.35 ± 5.86 ($p = 0.063$, not statistically significant).
- **3 months:** Suprapatellar: 81.55 ± 4.54, Infrapatellar: 77.6 ± 6.29 ($p = 0.028$, statistically significant).
- **6 months:** Suprapatellar: 92.2 ± 5.35, Infrapatellar: 87.95 ± 5.34 ($p = 0.016$, statistically significant).
- These results indicate faster and better functional knee recovery in the suprapatellar group.

Lower Extremity Functional Scale (LEFS) Score:

- Similar trends were observed with the LEFS score, reflecting better overall lower extremity function in the suprapatellar group.
- **1 month:** Suprapatellar: 68.80 ± 7.21, Infrapatellar: 64.65 ± 8.00 ($p = 0.075$, not statistically significant).
- **3 months:** Suprapatellar: 81.55 ± 5.69, Infrapatellar: 76.55 ± 5.77 ($p = 0.016$, statistically significant).
- **6 months:** Suprapatellar: 88.20 ± 4.54, Infrapatellar: 82.10 ± 5.86 ($p = 0.025$, statistically significant).
- These results demonstrate a significant functional advantage for the suprapatellar group, particularly at 3 and 6 months.

Pain Outcomes:

Visual Analog Scale (VAS) Score:

- The suprapatellar group reported consistently lower pain levels throughout the follow-up period.
- **1 month:** Suprapatellar: 4.5 ± 0.50, Infrapatellar: 5.0 ± 0.70 ($p = 0.020$, statistically significant).
- **3 months:** Suprapatellar: 3.0 ± 0.40, Infrapatellar: 3.50 ± 0.60 ($p = 0.003$, statistically significant).

- **6 months:** Suprapatellar: 2.0 ± 0.30, Infrapatellar: 2.50 ± 0.50 (p = 0.001, statistically significant).
- These findings indicate significantly less post-operative pain in the suprapatellar group.

Radiological Outcomes:

- The suprapatellar group consistently demonstrated better alignment success rates.
- **1 month:** Suprapatellar: 95%, Infrapatellar: 90% (p = 0.0001, statistically significant).
- **3 months:** Suprapatellar: 98%, Infrapatellar: 92%.
- **6 months:** Suprapatellar: 99%, Infrapatellar: 91%.
- Complications (infection, non-union) in the infrapatellar group negatively impacted radiological outcomes.
- The suprapatellar group exhibited fewer complications (delayed union) and better alignment and union rates.
- The results remained superior for the suprapatellar group, even when accounting for loss to follow up.

Table 1: Comparison of post-operative Lysholm Score between two groups

Duration	Groups	Mean ± Sd	Std error mean	t-test	P value	95% confidence Interval Lower	Upper
1 month	Suprapatellar	68.8±5.51	0.94	1.92	0.063	-0.12	7.02
	Infrapatellar	65.35±5.86	1.01				
3 month	Suprapatellar	81.55±4.54	0.91	2.28	0.028	0.51	7.39
	Infrapatellar	77.6±6.29	1.02				
6 month	Suprapatellar	92.2±5.35	1.11	2.52	0.016	0.83	7.67
	Infrapatellar	87.95±5.34	1.18				

Table 2: Comparison of post-operative LEFS score between two groups

Duration	Groups	Mean± Sd	Std error mean	t- test	P value	95% confidence Interval Lower	Upper
1 month	Suprapatellar	68.80± 7.21	1.61	1.85	0.075	-0.55	8.02
	Infrapatellar	64.65± 8.00	1.79				
3 month	Suprapatellar	81.55± 5.69	1.27	2.25	0.016	1.04	9.46
	Infrapatellar	76.55± 5.77	1.29				
6 month	Suprapatellar	88.20± 4.54	1.02	2.36	0.025	0.84	11.76
	Infrapatellar	82.10± 5.86	1.31				

Table 3: Comparison of post-operative VAS between two groups

Duration	Groups	Mean ± Sd	Std error mean	t- test	P value	95% confidence Interval Lower	Upper
1 month	Suprapatellar	4.50± 0.50	0.11	-2.41	0.020	-0.91	-0.09
	Infrapatellar	5.00± 0.70	0.16				
3 month	Suprapatellar	3.00± 0.40	0.09	-3.12	0.003	-0.82	-0.18
	Infrapatellar	3.50± 0.60	0.13				
6 month	Suprapatellar	2.00± 0.30	0.07	-3.57	0.001	-0.77	-0.23
	Infrapatellar	2.50± 0.50	0.12				

Table 4: Comparison of post-operative radiological outcomes between two groups

Duration	Groups	Mean ± Sd	Std error mean	t-test	P value	95% confidence Interval lower	Upper
1 month	Suprapatellar	95± 3	0.67	4.45	0.0001	2.16	7.84
	Infrapatellar	90± 4	0.89				
3 month	Suprapatellar	98± 2	0.47	4.78	0.0002	3.16	8.84
	Infrapatellar	92± 5	1.12				
6 month	Suprapatellar	99± 1	0.24	5.35	<0.001	3.30	7.70
	Infrapatellar	91± 5	1.21				

mobilization and fracture healing, has become the standard of care for these fractures. However, the optimal entry point remains a subject of debate due to variations in surgical technique, potential complications, and post-operative outcomes. In our study, the average age of patients was comparable between the SPN and IPN groups, indicating a similar patient demographic. The distribution of injury mechanisms highlighted the prevalence of falls from height and sports-related injuries, underscoring the diverse patient population affected by these fractures. Functional outcomes, assessed using the Lysholm Knee Score, LEFS, and VAS, revealed significant differences between the two groups. Notably, the SPN group demonstrated superior functional recovery at 3 and 6 months, as evidenced by higher Lysholm Knee and LEFS scores. This aligns with findings from Courtney et al. (2015), who suggested that suprapatellar nailing improves knee function, particularly in complex fractures requiring precise alignment. The superior outcomes in the SPN group are likely attributable to the reduced disruption of the patellar tendon and extensor mechanism, minimizing soft tissue stress. Furthermore, the SPN group reported significantly lower pain levels, as indicated by consistently lower VAS scores. This finding is consistent with Rakesh et al. (2023), who observed that the suprapatellar approach reduces anterior knee pain, a common complication associated with infrapatellar nailing due to patellar tendon compression. Radiologically, the SPN group exhibited superior fracture union and alignment rates compared to the IPN group. The higher union rate in the SPN group suggests improved fracture reduction and healing, potentially due to better control over fracture fragments. The superior alignment rates in the SPN group, as noted by Courtney et al. (2015) and Tejwani et al. (2014), reinforce the advantage of this approach in minimizing malalignment. Complication rates differed between the two groups. The IPN group experienced higher rates of infection and non-union, which is consistent with previous studies highlighting the increased risk of soft tissue complications with this approach. Rakesh et al. (2023) and Xu et al. (2019) have reported that the proximity of the surgical entry point to the patellar tendon in the infrapatellar technique can lead to increased anterior knee pain, infection, delayed union, and non-union. The SPN group, on the other hand, experienced only one case of delayed union, suggesting a lower risk of such complications. Our findings are consistent with Wang et al. (2018), who reported that the suprapatellar technique resulted in reduced fracture risk, improved knee functional recovery, decreased knee pain, and shorter fluoroscopy time. However, our results differ from Gao et al. (2022), who found no significant difference in Lysholm and VAS scores between the two groups. These discrepancies may be attributed to variations in surgical techniques, patient selection, and sample sizes across studies. The limitations of our study include the relatively small sample size, which may limit the generalizability of our findings. Additionally, the study was conducted at a single center, which may introduce selection bias. Future studies with larger sample sizes and multicenter designs are warranted to validate our findings. Long-term follow-up studies are also needed to assess the durability of functional and radiological outcomes. In conclusion, our study demonstrates that suprapatellar intramedullary nailing for proximal tibia extra-articular fractures yields superior functional and radiological outcomes compared to the infrapatellar approach. The SPN technique resulted in improved knee function, reduced pain, better fracture union and alignment rates, and fewer complications. These findings suggest that the suprapatellar approach may be preferable for treating proximal tibia extra-articular fractures. However, surgeons should consider patient-specific factors and their own experience when selecting the appropriate surgical technique

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